FEB 2 6 2004

Exhibit #1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K040252

1. **Submitter's Identification:**

Rex Medical
555 North Lane
Suite 6101
Conshohocken, PA 19428
(610) 940-0665

Contact: Ms. Susan Goldstein-Falk
Alternate contact: Ms. Denise Flamer

Date Summary Prepared:

January 14, 2004

2. **Name of the Device:**

Rex Medical Cleaner™ Rotational Thrombectomy System Kit

3. **Predicate Device Information:**

Trade Name	510(k) Number
Rex Medical Cleaner™ Rotational Thrombectomy System	K031610
Rex Medical Inner-Lock™ Introducer Sheath	K022170
Rex Medical Short Introducer Sheath	K032569
Cleaner II Rotational Thrombectomy System	K033793
Arrow-Trerotola™ PTD Percutaneous Thrombolytic Device	K990829
Arrow-Trerotola™ PTD Percutaneous Thrombolytic Device	K970080

4. **Device Description:**

The Rex Medical Cleaner™ Rotational Thrombectomy System Kit is a battery operated, hand held, wall contacting, rotational thrombectomy device which provides an effective means to restore patency to occluded synthetic dialysis grafts. The rotational wire, with integrated soft distal tip, provides an atraumatic approach to mechanical thrombectomy. The Cleaner™ macerates clot into particulate size that is not harmful to the patient.

5. **Intended Use:**

The Cleaner™ Rotational Thrombectomy System Kit is designed for mechanical declotting in synthetic dialysis access grafts.

6. **Comparison to Predicate Devices:**

The Cleaner™ Rotational Thrombectomy System Kit is identical to the predicate Cleaner™ Rotational Thrombectomy System with the exception that the kit incorporates either an Inner-Lock™ Introducer Sheath or a Short Introducer Sheath.

The rotational velocity of the wire was originally specified as 4000 ± 500 RPM for the Cleaner™ Rotational Thrombectomy System. The rotational velocity of the wire for the Cleaner™ Rotational Thrombectomy System Kit is being specified as 3000 – 4500 RPM based on additional verification testing.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Verification testing was performed to ensure that the addition of the Inner-Lock Introducer Sheath or the Short Introducer Sheath did not adversely affect the use of the Cleaner™ Rotational Thrombectomy System. Verification testing was also performed to ensure that the change in the rotational velocity of the wire did not affect the safety and effectiveness of the Cleaner™ Rotational Thrombectomy System. Testing proved that there is no effect on the safety and efficacy of the Cleaner™ Rotational Thrombectomy System Kit with the additions and modification noted above.

K040252

8. **Conclusions:**

The subject device, Rex Medical Cleaner™ Rotational Thrombectomy System Kit, has the same intended use as the predicate devices. Verification testing contained in our submission demonstrates that there is no difference in the technological characteristics of the device, thereby not raising any new questions of safety or effectiveness. Thus, the Rex Medical Cleaner™ Rotational Thrombectomy System Kit is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 26 2004

Rex Medical
c/o Ms. Susan D. Goldstein-Falk
Official Correspondent for Rex Medical
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

Re: K040252
Trade Name: Cleaner Rotational Thrombectomy System Kit
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: II (two)
Product Code: MCW
Dated: January 26, 2004
Received: February 04, 2004

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Bochner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K# 040252

Device Name: Rex Medical Cleaner ™ Rotational Thrombectomy System Kit

Indications For Use:

The Cleaner ™ Rotational Thrombectomy System Kit is designed for mechanical declotting in synthetic dialysis access grafts.

Prescription Use X (Per 21 CFR 801 Subpart D) OR **Over-The Counter Use_____** (21 CFT 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vadnais

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040252